IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

AVANIR PHARMACEUTICALS, INC., AVANIR HOLDING COMPANY, AND CENTER FOR NEUROLOGIC STUDY, Plaintiffs, v. ACTAVIS SOUTH ATLANTIC LLC, ACTAVIS, INC., PAR PHARMACEUTICAL, INC., PAR PHARMACEUTICAL COMPANIES, INC., IMPAX LABORATORIES, INC., WOCKHARDT, LTD., WOCKHARDT USA, LLC, WATSON PHARMACEUTICALS, INC., WATSON LABORATORIES, INC., AND WATSON PHARMA, INC., Defendants.	C.A. No. 11-704-LPS (CONSOLIDATED)

JOINT MOTION FOR LEAVE TO SUPPLEMENT THE TRIAL RECORD

Pursuant to Federal Rule 52(b), the parties jointly submit this request for the Court to supplement the trial record in this action to include a December 10, 2013 press release regarding the results of Avanir's PRIME Study and to include related proposed findings of fact.

I. BACKGROUND

On December 10, 2013, Avanir issued a press release disclosing the results of its Phase II PRIME study. *Available at* http://ir.avanir.com/phoenix.zhtml?c=61699&p=irol-newsArticle&ID=1883673&highlight= (enclosed as JTX 1). The information in the Avanir press release was not available to the parties during trial.

II. ARGUMENT

"A motion to amend findings of fact under Rule 52(b) may, however, be made prior to the entry of judgment." *Greenwood v. Greenwood*, 234 F.2d 276, 278 (3d Cir. 1956) (citations

omitted).[1] Reopening a closed evidentiary record on a matter still under advisement is committed to the trial court's discretion. *See Zenith Radio Corp. v. Hazeltine Research, Inc.*, 401 U.S. 321, 331 (1971) ("Like a motion under Rule 15(a) to amend the pleadings, a motion to reopen to submit additional proof is addressed to his sound discretion.") (citations omitted); *Williams v. Apfel*, No. 99-039-SLR, 2001 WL 657283, at *1 (D. Del. Mar. 30, 2001). The Third Circuit has described Rule 52(b) as "allow[ing] the court to correct plain errors of law or fact, or, in limited situations, allow[ing] the parties to present newly discovered evidence." *Moss v. Potter*, No. 07-2779, 2007 WL 2900551, at *2 n.2 (3d Cir. Oct. 3, 2007); *see also Gutierrez v. Gonzales*, 125 F. App'x 406, 417 (3d Cir. 2005).

The parties agree the Avanir press release is admissible. The parties had no access to the information in the Avanir press release during the trial. *See, e.g.*, D.I. 447 at PFF 227; D.I. 446 at 40-41. Therefore, the parties could not have introduced the Avanir press release at trial. As such, good cause exists to admit the press release now.

III. CONCLUSION

For the foregoing reasons, the parties respectfully request permission to supplement the trial record by adding JTX 1. Additionally, the parties submit the following supplemental Proposed Findings of Fact:

Plaintiffs' Supplemental Proposed Findings of Fact

231. In the PRIME study, Avanir's phase II clinical trial to assess the safety and efficacy of various DM/Q combinations for the treatment of central neuropathic pain—a type of chronic and intractable pain—in patients with multiple sclerosis, patients given doses of 20 mg

[1] Federal Rule 52(b) provides, in relevant part, that "[o]n a party's motion filed no later than 28 days after entry of judgment, the court may . . . make additional findings . . . ." Fed. R. Civ. P. 52(b).

DM and 10 mg Q showed statistically significant reduction in pain compared to baseline, and those doses were safe and well-tolerated. (*See* JTX-1.)

232. The PRIME study results were comparable to pain reduction seen in other DM/Q studies in other types of chronic or intractable pain. (*See* JTX-1; FF 228.)

Defendants' Supplemental Proposed Findings of Fact

328. On December 10, 2013, Avanir disclosed the results of its Phase II PRIME Study for the treatment of central neuropathic pain in patients with multiple sclerosis. *See* JTX 1. Avanir admitted "there was no difference between the treatment arms [using AVP-923, which included '20mg DM/10mg Q'] and placebo," and "the treatment of central neuropathic pain in patients with multiple sclerosis did not meet the primary efficacy endpoint." JTX 1.

329. Nuedexta, which contains the same AVP-923 dosage of 20mg DM/10mg Q used in the Phase II PRIME Study, is not capable of treating pain better than a placebo. JTX 1. Accordingly, Defendants' ANDA products are not capable of treating pain, as required in the asserted claims of the '115 patent.

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Dated: December 17, 2013